REMARKS

Claims 2-46 are pending, and of these claims 37-41 and 44-46 are independent, claims 2-36 and 42-43 are dependent; of which claims 2-36 depend from claim 40 and newly added claims 42-43 depend from claim 41. Claim 1 has been cancelled without prejudice. Claims 37-39 have been amended to more clearly define the Applicants' invention. Dependent claims 2-5, 23, and 25-27 have been amended to more clearly define the Applicants' invention and to amend their dependency to newly added claim 40. Newly added independent claims 40, 41 and 44-46 have been added to more clearly define the Applicants' invention. No new matter is added. Favorable reconsideration and allowance of the claims are requested.

The Office Action rejects claims 1-19, 21-26 and 28-39 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,657,255 issued to Fink et al. ("Fink"). The Office Action rejects claims 20 and 27 under 35 U.S.C. §103(a) as being obvious in light of U.S. Patent No. 5,657,255 issued to Fink et al. ("Fink").

The § 102(e) Rejections

A. Fink et al.

Claims 1-19, 21-26, and 28-39 were rejected as anticipated by U.S. Patent 5,627,255 issued to Fink et al. Claim 1 has been cancelled without prejudice. Claims 37-39 are independent. Claims 2-36 are dependent and depend from newly added claim 40. Fink et al. discloses a system for modeling a multi-variable biological system wherein the model is built by linking one or more biological subsystems together. The resulting model is used to understand the interaction between the various subsystems, how one subsystem effects and/or relates to the other subsystems and how the resultant system reacts to a drug or treatment regimen input, with the ultimate goal of predicting, in silica, what will happen in an actual person or biological system. The system in Fink et al. does not generate states that are predetermined.

Applicants respectfully submit that amended Claims 37-39, and newly added claims 40, 41, and 44-46 all of which are independent, are not anticipated by Fink et al. Because claims 2-36 and 42-43 depend from newly added independent claims 40 and 41, respectively, Applicants respectfully submit that these claims are also not anticipated by Fink et al. In Fink et al. a user specifies a particular disease aspect to model, and from this specification a determination is made as to which building blocks to use in modeling the particular disease aspect. Once the building blocks are assembled the model is then used to predict what will happen in a real biological system. In Fink et al. the outcome of the model is not a predetermined state. In contrast, in accordance with at least one embodiment of the invention, the present invention provides a method and a system in which each state of the system is a predetermined state.

Moreover, the present invention provides a method and a system to evaluate the user, in part, based on a user profile. The user's profile determines the testing area and thus the patient history. Fink et al., on the other hand, is concerned with creating a model of a biological system and using the model to understand the specified system and how its component parts interact. In Fink et al. the user's knowledge and problem solving abilities are not being tested nor is the system created in response to the user's profile, in at least one embodiment of the present invention. The Examiner argues that column 13, lines 18-20 of Fink clearly teach evaluating the user in response to at least one intervention input by the user and predetermined criteria. However, column 13, lines 18-20 of Fink only discloses a drug or treatment regimen as input and observing the model (i.e., patient or patients) as a result of the drug or treatment regiment and not evaluating the user. Fink only discloses observations of its model as a function of input and does not teach the evaluation of the user (i.e., the actual operator of the model).

The Examiner argues that column 6, lines 49-56 teach evaluating a user. However, column 6, lines 49-56 only teach development of a model to identify a new target for drug development and does not teach evaluating the user. Independent claims 37-41 and 44-46 have been amended to more clearly define the Applicants' invention in this regard. Accordingly, Fink et al. cannot anticipate the presently claimed invention.

Further, Fink et al. does not teach generating a patient history. Fink et al. discloses a model created by linking together a number of biological subsystems to create an overall system in which it is possible to drill down from the highest level system to the lower level subsystems,

i.e., tracing a biological variation back to a specific genetic variation. Applicants' respectfully disagree with the Examiner's remarks stating that tracing a biological variation back to a specific genetic variation is equivalent to generating a patient history. A patient history is dependent on many other factors aside from specific genetic variation, such as for example, past treatment programs and environmental factors. Moreover, Applicants' respectfully submit that independent Claims 37-41 and 44-46, and thus dependent claims 2-36 and 42-43, consider more than specific genetic variation when generating a patient history, such as for example, the testing area is considered when generating a patient history in accordance with at least one embodiment of the invention. Another example demonstrating that patient history includes more than specific genetic variation, and in accordance with the present invention, is the existence of an overweight condition in a patient.

For the above reasons, Applicants respectfully disagrees with the Examiner's statement that tracing variation back to a specific genetic variation is equivalent to generating a patient history as claimed, according to one embodiment, in the present invention. Accordingly, Applicants request the Examiner to provide an affidavit under 37 CFR §1.104(d)(2) describing in detail why these features are equivalent or a prior art reference showing same, in combination with the remaining features of independent claims 37-41 and 44-46.

Moreover, Fink et al. fails to disclose, for example, evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria. Fink et al. discloses a system capable of receiving input, in the form of a drug or treatment regimen, after which the model outputs the clinical status or clinical results from applying the treatment, however it is the model that is evaluated only. In the present invention, for example, the user is evaluated based on at least one intervention input by the user and the predetermined criteria.

Fink, in one embodiment, provides a model which provides a "means of collecting into dynamic executable format information regarding drug impact at molecular, and other levels, to predict what will happen at the patient level." (column 12, lines 33-36). This language indicates that the output from inputs to the model disclosed in Fink are not known patient conditions. Whereas, in the present invention, according to one embodiment, in order to evaluate a user based on at least one intervention, the user should be provided patient histories with known treatment pathways.

Claim 37 is directed to a system for simulating intervention to a patient having at least one health state and recites "accessing a profile for said user," "defining a test area in response to said profile," generating a patient history "selected from predetermined health states," and "evaluating the user" in response to "at least one intervention input by the user." The combination of features of independent claim 37 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

Claim 38 is directed to a computer program product and recites a "medium storing instructions for implementing a process driven by a computer." Claim 38 also recites "accessing a profile for said user," defining a test area, "generating a predetermined patient history responsive to the test area," and "evaluating the user" in response to "at least one intervention input by the user." The combination of features of independent claim 38 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

Claim 39 is directed to a method for evaluating the interventions by a user to a simulation and recites "accessing a profile for said user, defining a test area to evaluate the user ... generating a predetermined patient history responsive to the test area .. and evaluating the user" in response "to at least one intervention by the user." The combination of features of independent claim 39 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

Claim 40 is directed to a method for evaluating "a user's problem solving abilities in response to a complex system" and recites "accessing a profile for said user; selecting a testing area ... generating a patient history," comprising "predetermined set of health states" and "evaluating said user" in response to "at least one predetermined criteria and said at least one intervention." The combination of features of independent claim 40 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

Claim 41 is directed to a method for "testing a user's problem solving abilities in response to a complex system" and recites "generating an initial patient history state, wherein said initial patient history state comprises a predetermined set of health states; evolving the initial patient history state to a predetermined subsequent patient history health state," "receiving at least one intervention input by said user," and evaluating said user" response to "said at least one intervention." The combination of features of independent claim 41 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

Claim 44 is directed to a method for "training a user regarding the operation of a complex system" and recites "generating an initial patient history state" "iterating through a prescribed treatment protocol with said user." The combination of features of independent claim 44 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

Claim 45 is directed to a method for "simulating a complex system" and recites "generating an initial patient history state" "evolving ... the initial patient history state to a predetermined subsequent patient history state" and "observing a full fidelity model of a patient" "so as to extract user inputs and patient responses." The combination of features of independent claim 45 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

Claim 46 is directed to a method for evaluating "a user's problem solving abilities in response to a complex system" and recites "generating multiple instances of patients representing a clinical scenario" "wherein each of said patients have an initial patient history state" "evolving at least one of each of said patients' initial patient history state to a predetermined subsequent patient history state" and "evaluating said user" in response to at least one intervention by said user." The combination of features of independent claim 46 when interpreted as a whole, is submitted to patentably distinguish over the prior art.

In view of the above, Applicants respectfully submits that none of the prior art references cited by the Examiner shows or suggests the above noted features in combination with the remaining features as well as the combination of features recited in the remaining claims when each claim is interpreted as a whole. Therefore withdrawal of the instant rejections is respectfully requested.

Accordingly, Applicants deem this rejection overcome and respectfully request withdrawal thereof. The remaining dependent claims should be also allowed at least for the reasons noted herein, as well as the additional limitations cited therein, in combination.
In addition to the above, the present invention provides benefits over the prior art cited by the Examiner. For example, the present invention allows insurance companies to determine whether specific physicians are practicing cost effective medicine. In addition, the present invention allows for the objective determination of medical budgets for the treatment of different types of non-wellness states, such as for example, the annual cost of care for an asthmatic patient. Further, the present invention allows physicians to train or rehearse a desirable behavior, such as

prescribing aspirin for long term care after a patient has a heart attack, and therefore increase the occurrence of the desirable behavior when acting on a real patient. Therefore, for these reasons as well, Applicants respectfully submits that the instant claims are patentable over the prior art of record.

As the dependent claims recited by the present application also include evaluating a user based in part on at least one intervention by the user in response to a generated patient history, arguments similar to those presented above in support of the independent claims apply to the dependent claims as well. Furthermore, each of these claims includes additional features that are independently patentable as well. For instance, in claims 2, 3, 4, 18, 24, 42, and 43 evolving the patient history to a predetermined health state occurs in response to at least one user intervention.

Advantageously, evolving the patient history allows for the creation of a treatment history which allows users to be evaluated based on their treatment of chronic illness or in long term care situations such as diabetes. The step of evolving the patient history to a predetermined health state in response to at least one user interaction also provides of the advantage of observing a long term care situation in the presence of other cofactors that can influence the state of wellness of the patient, such as for example, the effect of obesity on the treatment of diabetes. In this manner, the present invention allows a user/physician to practice treating long term care situations under real world conditions instead of as isolated disease states. Applicant submits that this feature, when taken with the remaining features and when each claim is taken as a whole, is also not disclosed or suggested by the prior art references of record. More specifically, none of the references of record disclose or suggest evaluating a user based in part on at least one intervention by the user in response to a generated patient history, as recited in claims 2, 3, 4, 18, 24, 42, and 43. Thus, for these reasons as well, Applicants respectfully submits that the instant claims are patentable over the prior art of record.

The §103(a) Rejections

Claims 20 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fink et al. Applicant respectfully traverses this rejection.

For the same reasons noted above, Fink et al. does not teach the computer implemented simulation and evaluation method according to claim 5 and therefore it would not have been obvious to one of ordinary skill in the art to include any one of the specific relationships listed in claim 20.

Further, and again for the same reasons noted above, Fink et al. does not teach the computer implemented simulation and evaluation method according to newly added independent claim 40, from which claim 5 depends, and therefore, it would not have been obvious to one of ordinary skill in the art to apply a Monte Carlo process to generate a plurality of potential patient histories as recited in claim 27 in combination. The Examiner admits in the office action that these features are not shown or suggested by Fink et al.

In addition, Applicants strongly disagree with the Examiner's personal findings that the specific features recited in claim 27 are well known. First, Fink, et al. does not teach the combination of selecting genetic information of the patient, generating a patient history, and evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria, or using a Monte Carlo process in combination. Accordingly, Applicant requests the Examiner to provide an affidavit under 37 CFR §1.104(d)(2) describing in detail why these features are well known or a prior art reference showing same, in combination with the remaining features of claim 27.

CONCLUSION

For all the reasons advanced above, Applicant respectfully submits that the rejections have been overcome and should be withdrawn.

For all the reasons advanced above, Applicant respectfully submits that the Application is in condition for allowance, and that such action is earnestly solicited.

Applicant also intends on antedating the Fink et al. patents in a future Response.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment to deposit account no. 08-0219.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to deposit account no. 08-0219.

Respectfully submitted,

HALE AND DORR LLP

Irah H. Donner
Registration No. 35,120

1455 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
TEL 202.942.8585
FAX 202.942.8484
Date: 7/8/02
IHD:sgs/110346-100 US2
175033v1

Attachment A

(amendments indicated with brackets and underlines)

2. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, further comprising the steps of:

(g) evolving the patient to a predetermined health state responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state; and

(h) evaluating the user responsive to the at least one intervention input by the user, the at least one subsequent health state, and the predetermined criteria.

3. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, further comprising the steps of:

(g) evolving the patient to a predetermined health state responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state; and

(h) receiving at least one other intervention input by the user; and

(i) evaluating the user responsive to at least one of the at least one intervention input by the user, the at least one other intervention input by the user, the at least one subsequent health state, and the predetermined criteria.

4. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, further comprising the steps of:

(g) evolving the patient to a predetermined health state responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state;

(h) receiving at least one other intervention input by the user;

(i) evolving the patient responsive to the at least one intervention, the genetic information and the patient history to at least one other subsequent health state; and

(j) evaluating the user responsive to at least one of the at least one intervention input by the user, the at least one subsequent health state, the at least one other subsequent health state, and the predetermined criteria.

5. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, wherein said generating step (d) further comprises the step of generating the patient history responsive to the test area, the genetic information, and an entity relationship model.

23. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, wherein said generating patient history step (d) is executed once for each simulation to generate the patient history used in said computer implemented simulation and evaluation method.

25. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, wherein said generating step (d) generates the patient history comprising a progression of health states and risk factors traversed by the patient from a normal health condition to a specified health condition.

26. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, wherein said generating step (d) iteratively generates the patient history backwards in time from a specified health condition to a normal health condition including successive precursor health states and onset times therebetween.

27. (Amended Once) A computer implemented simulation and evaluation method according to claim [1] 40, wherein said generating step (d) generates the patient history using a Monte Carlo process to multiple stochastic trees to generate a plurality of potential patient histories to be used in said computer implemented simulation and evaluation method.

37. (Amended Once) A computer simulation and evaluation system for simulating interventions including active and passive intervention to a patient having a health state by a user, and for evaluating the interventions responsive to predetermined criteria and the interventions, comprising:

a knowledge database storing patient health characteristics including at least one of population, record, agents of change, health states, findings and courses of action;

a presentation system providing access to the computer simulation and evaluation system by the user; and

a patient simulation system adapted to be connectable to said presentation system and said knowledge database, said patient simulation system performing the functions:

(a) defining a test area in response to said profile and selecting genetic information of the patient responsive to the test area and the knowledge database;

(b) accessing a profile for said user;

[(b)](c)generating a patient history responsive to the test area and the genetic information, wherein said patient history is selected from predetermined health states;

[(c)](d)receiving at least one intervention input by the user; and

[(d)](e)evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria.

38. (Amended Once) A computer readable tangible medium storing instructions for implementing a process driven by a computer, the process simulating interventions initiated by a user, the interventions including active and passive interventions to a patient having a health state, and the process evaluating the interventions responsive to predetermined criteria and the interventions, the instructions comprising the steps of:

(a) accessing a profile for said user;

(b) accessing the computer implemented simulation and evaluation method by the user;

(c) defining a test area to evaluate the user by the computer implemented simulation and evaluation method responsive to at least one of predetermined criteria and a user profile;

(d) selecting genetic information of the patient responsive to the test area;

(e) generating a predetermined patient history responsive to the test area and the genetic information;

(f) receiving at least one intervention input by the user; and

(g) evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria.

39. (Amended Once) A computer implemented simulation and evaluation method simulates interventions to a patient by a user, and evaluates the interventions responsive to predetermined criteria and the intervention, said method comprising the steps of accessing a profile for said user, defining a test area to evaluate the user responsive to at least one of predetermined criteria and a user profile, selecting genetic information of the patient responsive to the test area, generating a predetermined patient history responsive to the test area and the genetic information, receiving at least one intervention input by the user, and evaluating the user responsive to the at least one intervention and the predetermined criteria.

Please add the following new claims:

SUB D1

40. (New) A computer implemented simulation and evaluation method for testing a user's problem solving abilities in response to a complex system, such as a patient having at least one health state, such method comprising the steps of:

(a) accessing a profile for said user;

(b) selecting a testing area to evaluate said user on at least one predetermined criterion responsive to said profile;

(c) selecting genetic information of a patient responsive to said testing area;

(d) generating a patient history responsive to testing area and said genetic information, wherein said patient history comprises a predetermined set of health states;

(e) receiving at least one intervention input by user, wherein said at least one intervention includes passive and active interventions; and

(f) evaluating said user responsive to said at least one predetermined criteria and said at least one intervention.

41. (New) A computer implemented simulation and evaluation method for testing a user's problem solving abilities in response to a complex system, such as a patient having at least one predetermined health state, such method comprising the steps of:

(a) generating an initial patient history state, wherein said initial patient history state comprises a predetermined set of health states;

(b) evolving the initial patient history state to a predetermined subsequent patient history health state;

(c) receiving at least one intervention input by said user, wherein said at least one intervention includes passive and active interventions; and

(d) evaluating said user responsive to said at least one intervention.

42. (New) The method according to claim 41, wherein evolving the initial patient history state to said predetermined subsequent patient history state occurs over a finite stochastically determined time period.

43. (New) The method according to claim 41, further comprising the step of repeating said evolving step and receiving step a plurality of times.

44. (New) A computer implemented method for training a user regarding the operation of a complex system, such as a patient having at least one predetermined health state, such method comprising the steps of:

(a) generating an initial patient history state, wherein said initial patient history state comprises a predetermined set of health states; and

(b) iterating through a prescribed treatment protocol with said user, wherein said iterating step comprises evolving, through at least one intermediate health state, the initial patient history state to a predetermined subsequent patient history health state.

45. (New) A computer implemented method for simulating a complex system, such as a patient having at least one predetermined health state such method comprising the steps of:

(a) generating an initial patient history state, wherein said initial patient history state comprises a predetermined set of health states;

(b) evolving, through at least one intermediate health state, the initial patient history state to a predetermined subsequent patient history health state; and

(c) observing a full fidelity model of a patient having at least one predetermined health state so as to extract user inputs and patient responses at each said evolving step.

46. (New) A computer implemented simulation and evaluation method for testing a user's problem solving abilities in response to a complex system, such as a group of patients, wherein each patient in said group has at least one health state, such method comprises the steps of:

(a) generating multiple instances of patients representing a clinical scenario, wherein each of said patients have an initial patient history state comprising a predetermined set of health states;

(b) evolving at least one of each of said patients' initial patient history state to a predetermined subsequent patient history health state;

(c) receiving at least one intervention input by said user, wherein said at least one intervention includes passive and active interventions; and

(d) evaluating said user responsive to said at least one intervention.